BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the proposed amendment of ARM 24.174.301 and 24.174.303 definitions, 24.174.401 and 24.174.403 general provisions, 24.174.503, 24.174.514, 24.174.521, 24.174.522, 24.174.523 and 24.174.524 licensing, 24.174.603 and 24.174.612 internship regulations, 24.174.705 and 24.174.711 pharmacy technicians, 24.174.801, 24.174.806 and 24.174.814 certified pharmacies, 24.174.1002 mail service pharmacies, 24.174.1107 and 24.174.1111 institutional pharmacies, 24.174.1201, 24.174.1202, 24.174.1211 and 24.174.1212 wholesale drug distributors licensing, 24.174.1401 dangerous drugs, 24.174.2101 renewals and continuing education, 24.174.2401 screening panel, and the proposed adoption of NEW RULE I inactive license, NEW RULE II telepharmacy operations, NEW RULE III remote telepharmacy dispensing machine sites, NEW RULE IV central filling by hub pharmacies, NEW RULE V ambulatory surgical facilities and NEW RULE VI fee abatement	)	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT AND ADOPTION

TO: All Concerned Persons

1. On February 2, 2006, at 10:00 a.m., a public hearing will be held in room 489, Park Avenue Building, 301 South Park, Helena, Montana to consider the proposed amendment and adoption of the above-stated rules.

2. The Department of Labor and Industry (Department) will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, contact the Board of Pharmacy (Board) no later than 5:00 p.m. on January 27, 2006, to advise us of the nature of the accommodation that you need. Please contact Marilyn Kelly-Clark, Board of Pharmacy, 301 South Park, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2355; Montana Relay

1-800-253-4091; TDD (406) 444-2978; facsimile (406) 841-2305; e-mail dlibsdpha@mt.gov.

3. The rules proposed to be amended provide as follows, stricken matter interlined, new matter underlined:

24.174.301 DEFINITIONS In addition to the terms defined in 37-7-101, MCA, the following definitions apply to the rules in this chapter.

(1) "Ambulatory surgical facility" means "outpatient center for surgical services" as defined at 50-5-101, MCA.

(1) through (4) remain the same but are renumbered (2) through (5).

(6) "DEA" means the Drug Enforcement Administration of the United States Department of Justice.

(5) through (24) remain the same but are renumbered (7) through (26).

(27) "Remote pharmacy" means a licensed pharmacy at which prescriptions may be filled or transmitted to a central hub pharmacy for filling and subsequent delivery to the remote site or the patient's home. Patient counseling by a pharmacist may occur at this site.

(28) "Remote telepharmacy dispensing machine site" means a licensed site containing prescription inventory which is secured in an automated dispensing device and which has access to its parent pharmacy and registered pharmacists via computer, video, and audio link at all times during business hours.

(29) "Remote telepharmacy site" means a licensed site staffed by a registered pharmacy technician with access to its parent pharmacy and registered pharmacists via computer, video, and audio link at all times during business hours.

(30) "Satellite pharmacy" means a specialized inpatient pharmacy staffed by a pharmacist which is adjacent to or near the department served and is connected via computer to the central institutional pharmacy.

(25) and (26) remain the same but are renumbered (31) and (32).

(33) "Verification audit" means a comparison and verification of written patient orders with medications removed for that patient.

AUTH: 37-7-201, MCA
IMP: 37-7-102, 37-7-201, 37-7-301, 37-7-321, 37-7-406, 50-32-314, MCA

REASON: The 1999 Montana Legislature enacted Chapter 273, Laws of 1999 (Senate Bill 478), an act requiring the Board to adopt rules providing for the registration of ambulatory surgical facilities. The bill was signed by the Governor and became effective on April 6, 1999, and was codified at 50-32-314, MCA. The 1999 Legislature also enacted Chapter 98, Laws of 1999 (Senate Bill 116), which changed the term "ambulatory surgical facilities" to "outpatient center for surgical services" in several places in statute. However, the terminology change was not made at 50-32-314, MCA. It is reasonably necessary for the Board to add a definition for "ambulatory surgical facilities" as identical to "outpatient center for surgical services". This amendment will clarify the meaning of the term as it pertains to the registration of these facilities under New Rule V and further implement the legislation. The Department intends to propose legislation during the 2007

legislative session to amend 50-32-314, MCA, and change the outdated term to “outpatient center for surgical services" to achieve consistency in statute.

It is reasonable and necessary to define “DEA” in one centralized location within the rules. The Board is adding the definition of “DEA” to this rule to provide simplicity and consistency throughout the rules by maintaining all definitions in a single rule.

The Board determined that it is necessary to include new definitions not previously enumerated. Adding definitions of several different types of pharmacy locations will enable licensees to better understand the provisions of telepharmacy regulation as set forth in New Rules II, III and IV.

The Board is proposing to add a definition of "verification audit" as the term is used in subchapter 11 of the Board rules. Addition of this definition will clarify the accounting process required following drug removal from night cabinets in institutional pharmacies. The remaining unaffected definitions are being renumbered within the rule accordingly. The implementation cites are being amended to accurately reflect all statutes implemented through the rule.

24.174.303 INTERNSHIP PROGRAM DEFINITIONS (1) through (5) remain the same.

(6) "Internship period" means 1500 hours of practical experience in an approved pharmacy, hospital or other facility. The intern must acquire a minimum of 20 hours experience per calendar week and may acquire a maximum of 48 hours experience per calendar week. ~~However, the~~ The student may acquire ~~up to 1000 hours concurrently with school attendance in approved courses, externships and clerkships, or demonstration projects in the B.S. program and~~ up to 1500 hours concurrently with school attendance in approved courses, externships and ~~clerkships~~ advanced practice, or demonstration projects in the Pharm.D. program.

(7) through (9) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: It is reasonable and necessary to amend the definition of “internship period” to conform with current pharmacy education standards throughout the United States. Previously, a pharmacy student could graduate with a bachelor of science in pharmacy (BS) degree, a doctor of pharmacy (Pharm.D.) degree or both. All schools of pharmacy within the United States have since changed to exclusively require the Pharm.D. degree, and reference to the BS program is no longer necessary. The term “clerkships” is being amended to “advanced practice” to comply with current terminology used in schools of pharmacy.

24.174.401 FEE SCHEDULE

(1) through (23) remain the same.

(24) Inactive pharmacist annual renewal fee	25
(25) Ambulatory surgical facility (original or renewal)	75

AUTH: 37-1-134, 37-7-201, 50-32-314, MCA
IMP: 37-1-134, 37-7-201, 37-7-302, ~~37-7-303,~~ 37-7-321, 37-7-703, 50-32-314, MCA

REASON: It is reasonable and necessary to amend this rule to add a fee for inactive pharmacist licensure, a new licensure category set forth in New Rule I. An estimated annual increase in revenue of $625.00 is anticipated, based upon an estimated 25 applicants with an annual inactive license fee of $25.00 per applicant.

Further, it is reasonably necessary to add a fee for the registration of ambulatory surgical facilities, as set forth in New Rule V, to further implement Senate Bill 478 of the 1999 Montana Legislature. An estimated annual increase in revenue of $1,125.00 is anticipated, based upon an estimated 15 facility registrants with an annual fee of $75.00 per applicant.

Authority and implementation cites are being amended to accurately reflect all statutes implemented through the rule, to provide the complete sources of the Board's rulemaking authority and to delete reference to a repealed statute.

24.174.403 CHANGE IN ADDRESS AND/OR EMPLOYMENT (1) All licensees ~~must~~ shall notify the board in writing within 10 days of any change in ~~location of their~~ employment~~, together with the~~ and/or any change of business or personal address.

AUTH: 37-7-201, MCA
IMP: 37-7-201, ~~37-7-303,~~ MCA

REASON: It is necessary for the Board to be able to contact licensees for license renewal, rulemaking notification and disciplinary purposes. The Board determined it is reasonably necessary to specify which address changes must be reported to the Board. Licensees may receive notifications from the Board at either their homes or places of employment, and the amended language will help ensure that all licensees' current addresses are maintained in the Board office. Implementation cites are being amended to accurately reflect all statutes implemented through the rule and to delete reference to a repealed statute.

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS

(1) through (5) remain the same.

(6) The authority of a pharmacist to administer immunizations may not be delegated~~.~~ ; however, an immunization-certified intern may immunize under the direct supervision of a pharmacist qualified under this chapter.

(7) remains the same.

AUTH: 37-7-101, 37-7-201, MCA
IMP: 37-7-101, 37-7-201, MCA

REASON: It is reasonable and necessary to amend this rule to clarify that pharmacy interns who have received training and certification from a Board approved program may perform immunizations while under the direct supervision of

a qualified pharmacist. Clarification of this topic has been sought by many practitioners throughout the state, as the University of Montana School of Pharmacy presently trains and certifies students to administer immunizations.

24.174.514 TRANSFER OF PRESCRIPTIONS (1) The manual transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(a) and (b) remain the same.

(2) The manual transfer of original prescription information for a controlled (dangerous) substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only, by following the procedures listed above. In addition ~~to~~:

(a) the transferring pharmacist shall record on the reverse of the invalidated prescription the DEA registration number of the pharmacy to which it was transferred~~,~~; and

(b) the pharmacist receiving the transferred prescription shall record the DEA registration number of the pharmacy from which the prescription information was transferred.

(3) The electronic transfer of prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(a) the transferring pharmacy shall:

(i) render the prescription void;

(ii) enter the name, address, and DEA number of the receiving pharmacy into the database of the transferring pharmacy;

(iii) inform the receiving pharmacy of:

(A) the date on which the prescription was written;

(B) the original number of refills;

(C) the number of refills remaining; and

(D) the date of the most recent refill; and

(iv) maintain a retrievable audit trail, including the date of transfer and initials or code of the transferring party, for a period of two years; and

(b) the receiving pharmacy shall maintain documentation including:

(i) a notation that the prescription was received by transfer;

(ii) the date on which the prescription was written;

(iii) the original prescription number of the transferred prescription;

(iv) the original number of refills, number of refills remaining, and the date of the most recent refill;

(v) the name, address, and DEA number of the transferring pharmacy;

(vi) all other prescription information required by state and federal laws and regulations;

(vii) a retrievable audit trail, including the date of transfer and initials or code of the receiving party, for a period of two years; and

(viii) a nonfading hard copy record of each prescription drug order transferred.

(4) The electronic transfer of original prescription information for a controlled (dangerous) substance listed in Schedules III, IV or V for the purpose of refill

dispensing is permissible between pharmacies on a one time basis only, by following the procedures listed above.

~~(3)~~ (5) Pharmacies accessing a common or shared electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the common or shared prescription file, provided, however, that any such common or shared file shall contain complete records of each prescription drug order and refill dispensed~~, . and further, that a~~ A hard copy record of each prescription drug order ~~transferred or~~ accessed for purposes of refilling shall be generated if necessary and maintained at the refilling pharmacy ~~refilling the prescription drug order or to which the prescription drug order is transferred~~. An easily retrievable audit trail which documents the location of each filling must be maintained and provisions must be made to assure that the number of authorized refills is not exceeded.

(a) and (b) remain the same.

(4) through (6) remain the same but are renumbered (6) through (8).

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: It is reasonably necessary to amend this rule to recognize and address the electronic transfer of prescriptions between pharmacies in addition to the traditional manual method of transfer. The Board has determined that electronic prescription transfer may be more efficient than manual transfer, and could potentially enhance the protection of public health and safety as transcription errors are avoided. As the procedures differ in several ways, and to add clarification, manual and electronic methods of prescription transfer have been separated into two distinct sections of the rule. Minor wording changes will enhance clarity of the rule and ease of reading.

24.174.521 RETURNED PRESCRIPTION (1) In the best interest of, and for the safety and protection of public health and ~~to~~ the pharmacy, no pharmacist shall place in stock for reuse or resale the contents of any prescription, which has been returned after leaving the pharmacy except as provided in ARM 24.174.1141.

AUTH: 37-7-201, 37-7-1401, MCA
IMP: 37-7-201, 37-7-1401, MCA

REASON: The 2001 Montana Legislature enacted Chapter 362, Laws of 2001 (Senate Bill 288), an act enabling dispensed medications to be returned and reused in specific circumstances. The bill was signed by the Governor on April 23, 2001, and became effective October 10, 2001. It is reasonable and necessary to amend this rule to acknowledge the exception exists, and to direct the reader to ARM 24.174.1141 for further explanation. Authority and implementation cites are being amended to accurately reflect all statutes implemented through the rule and to provide the complete sources of the Board's rulemaking authority.

24.174.522 ALTERNATE DELIVERY OF PRESCRIPTIONS (1) Under the provisions of 37-7-301, MCA, it shall be deemed a violation of the pharmacy law for any person or corporation holding a pharmacy license to participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by or delivered to any store, shop or any other establishment not licensed by the board as a ~~"certified pharmacy"~~ "pharmacy".

(a) and (b) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-301, MCA

REASON: It is reasonable and necessary to amend this rule to clarify and promote terminology consistency by striking "certified" from "certified pharmacy". Section 37-7-321, MCA, uses both "pharmacy" and "certified pharmacy" interchangeably, and 37-7-101(23), MCA, defines "pharmacy" with no differentiation from "certified pharmacy." There exists no definition, either in rule or statute, for "certified pharmacy." Deleting the word "certified" will lessen confusion among licensees. Implementation cites are being amended to accurately reflect all statutes implemented through the rule.

24.174.523 TRANSMISSION OF PRESCRIPTIONS BY ELECTRONIC MEANS (1) through (2)(b) remain the same.

(c) A signed prescription for a Schedule II substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII of the Social Security Act or a hospice program which is licensed by the state of Montana may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by electronic means. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The electronic transmission serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with ARM 24.174.512.

(3) remains the same.

(4) Prescriptions may be transmitted electronically directly from an authorized prescriber or his/her authorized agent to the pharmacy of the patient's choice without ~~intervention,~~ alteration by ~~a third~~ any other party, providing the following requirements are met:

(a) Both prescriber and pharmacist must have a secure (encrypted or encoded) system for electronic transmission from computer to computer that ensures patient confidentiality;

(b) through (f) remain the same.

~~(g) The electronic transmission shall maintain patient confidentiality;~~

~~(h)~~ (g) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice; ~~and~~

~~(i)~~ (h) The pharmacist is responsible for assuring the validity of the electronically transmitted prescription~~.~~;

(i) A pharmacist or pharmacy shall not enter into any agreement to provide or receive a computer or computer modem, personal digital assistant, facsimile

machine, or any other electronic device which would adversely affect a patient's freedom to select the pharmacy of the patient's choice; and

(j) A pharmacist or pharmacy shall not provide a computer or computer modem, personal digital assistant, facsimile machine, or any other electronic device to a prescriber or health care facility for the purpose of providing an incentive to refer patients to a particular pharmacy.

(5) remains the same.

AUTH: 37-7-201, 50-32-103, MCA
IMP: 37-7-102, 37-7-201, 50-32-208, MCA

REASON: It is reasonably necessary to amend this rule adding hospice programs to the list of circumstances in which a pharmacist may legally dispense a Schedule II controlled substance pursuant to an electronically transmitted prescription. The Code of Federal Regulations, Chapter 21, lists hospice programs as one of three exceptions to the written prescription requirements for Schedule II controlled substances. This important exception was inadvertently omitted from the original Board rule, and clarification on the matter has been requested by practitioners.

Further, it is reasonable and necessary to amend section (4) to clarify requirements for electronic prescription transmittal. With the increased use of electronic prescribing and current technology, many programs must route electronic messages through secure switching stations. The Board has no objection to systems requiring electronic rerouting during transmission as patient confidentiality and freedom of pharmacy choice are ensured and the prescription is not altered in its electronic progression from prescriber to pharmacy. The proposed rule change clarifies Board intent, protects both the intent of the prescriber and patient safety, and has been requested both by pharmacy practitioners and industry.

The Board determined it is reasonably necessary to add new subsections (4)(i) and (j) to address a situation in a Montana community where a pharmacy offered free computers and software programs to prescribing physicians to persuade the doctor to refer prescriptions directly to the pharmacy. The Board discussed this situation during two meetings and determined that such a practice would limit competition among pharmacies and place constraints on the patient's freedom to select a pharmacy. The Board concluded it is necessary to amend the rule in a proactive attempt to ensure patients' ability to choose the pharmacy filling their prescriptions.

24.174.524 NONINSTITUTIONAL COLLABORATIVE PRACTICE AGREEMENT REQUIREMENTS

(1) through (3) remain the same.

(4) Collaborative practice agreements approved by an institutional committee such as the pharmacy and therapeutics committee and that will be used solely for inpatients are exempt.

AUTH: ~~37-7-101,~~ 37-7-201, MCA
IMP: 37-7-101, 37-7-201, MCA

REASON: The 2001 Montana Legislature enacted Chapter 388, Laws of 2001 (House Bill 279), an act generally revising the practice of pharmacy. The bill was signed by the Governor on April 28, 2001 and became effective October 1, 2001. The legislation enabled pharmacists to enter into collaborative practice agreements with medical practitioners licensed to prescribe in Montana for purposes of their patient's medication management. The Board adopted ARM 24.174.524 in response to the legislation. Some confusion has arisen because hospital (institutional) pharmacists are frequently authorized to follow in-house protocols approved by the pharmacy and therapeutics committee within their institution. It was not the Board's intent to interfere with, or attempt to regulate, the many inpatient protocols unique to each institution in Montana. It is reasonably necessary to amend this rule and the catchphrase to clarify the Board's intent regarding the exemption. Authority cites are being amended to accurately reflect the statutory sources of the Board's rulemaking authority.

24.174.603 OUT-OF-STATE INTERNSHIP REQUIREMENTS

(1) Written request by the intern must be made to the board prior to commencing training at an out-of-state site.

(2) and (3) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: It is reasonably necessary to amend this rule to specify to whom requests must be submitted to avoid delays in processing and to lessen confusion among applicants.

24.174.612 REQUIRED FORMS AND REPORTS (1) remains the same.

(a) The "intern application" must be filed with the board by the intern before computed time is credited.

(b) The "internship experience affidavit", provided by the board, must be filed at the school of pharmacy by the intern at the end of the internship experience in a given site or after 500 hours, whichever comes first.

(c) The "evaluation of internship site" must be filed at the school of pharmacy by the intern at the completion of internship or externship experience in a given site or after 500 hours, whichever comes first.

(d) The "~~clerkship~~ advanced practice experience affidavit", provided by the board, must be filed at the school of pharmacy by the intern at the end of the academic year.

(e) The school of pharmacy shall forward to the board verification of 1500 hours of practical experience obtained through externship and advanced practice upon completion of those hours by each Pharm.D. candidate before application to take NAPLEX is made.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The Board determined it is reasonable and necessary to amend the rule to clarify to whom specific internship forms and reports must be submitted. Designating submission to either the Board or the intern's school of pharmacy will avoid delays in processing such forms and will lessen confusion among interns.

Because pharmacy education standards have recently changed throughout the United States and all pharmacy graduates now obtain a Pharm.D. degree, the required 1500 hours of internship experience can be obtained through scheduled rotations required by all Pharm.D. programs. Since student preceptors grade pharmacy externs and clerks at the end of each rotation, and the schools monitor reports and issue academic credit at the end of each rotation, the Board determined it is reasonable to amend this rule to simplify the reporting procedure. The amendment will require students to submit rotational reports to the schools only, rather than both the school and the Board.

Amending the rule to require the consolidation of periodic reports solely at the schools of pharmacy, rather than also at the Board office, will be simpler for pharmacy students and will help to eliminate unnecessary duplication of filing and maintaining documents. Further, the schools are better equipped than Board staff to monitor the accrual of intern hours and to ensure that students have completed the necessary requirements and are qualified to sit for the examination. The Board is obligated to license and regulate pharmacists and pharmacies and does not regulate the education of pharmacy students.

24.174.705 TASKS AND FUNCTIONS OF PHARMACY TECHNICIAN

(1) ~~A~~ Only a registered pharmacy technician may perform the following tasks or functions under the provisions of an approved utilization plan:

(a) through (e) remain the same.

~~(f) sell nonprescription drugs in their original containers without engaging in patient counseling, and refer all questions to the registered pharmacist;~~

(g) remains the same but is renumbered (f).

~~(h)~~ (g) a pharmacy technician may act as agent in charge of the pharmacy to assure its integrity when a registered pharmacist is not physically present, but may not perform any duties which require the exercise of the pharmacist's independent professional judgment. The technician may not be left in charge for more than 30 minutes; and

~~(i) receive and check in pharmaceuticals, including controlled substances, if the pharmacy technician initials and dates all invoices with the actual date the drugs were received;~~

~~(j) participate in the biennial inventory of controlled substances, providing a pharmacist supervises the process. The supervising pharmacist must co-sign the inventory with the pharmacy technician.~~

(k) remains the same but is renumbered (h).

(2) remains the same.

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA

REASON: It is reasonably necessary to amend this rule to update and clarify those tasks that only pharmacy technicians, as opposed to pharmacy clerks, may perform. The Board has received many comments and suggestions from pharmacists, pharmacy technicians and pharmacy clerks on this topic. Licensed pharmacists may delegate tasks to pharmacy technicians that do not require the exercise of the pharmacist's independent professional judgment and that are verified by the pharmacist. While many of the tasks listed may only be delegated by a pharmacist to a pharmacy technician, the Board determined that certain functions may safely be performed by pharmacy clerks. The Board has amended the rule accordingly, deleting those functions that can safely be performed by pharmacy clerks absent the objection of the pharmacist. Implementation cites are being amended to accurately reflect all statutes implemented through the rule.

24.174.711 RATIO OF PHARMACY TECHNICIANS TO SUPERVISING PHARMACISTS (1) ~~Except as provided in (2), a~~ A registered pharmacist in good standing may supervise the services of ~~only one~~ no more than four ~~technician~~ technicians at any time. The 1:4 pharmacist to pharmacy technician ratio may be revised by the board at any time for good cause.

~~(2) A registered pharmacist in good standing may supervise the services of two technicians at the same time if both are performing any of the following procedures:~~

~~(a) intravenous admixture and other sterile product preparation;~~

~~(b) filling of unit dose cassettes;~~

~~(c) prepackaging; or~~

~~(d) bulk compounding.~~

~~(3) A registered pharmacist in good standing may supervise the services of two technicians at the same time if one of the two technicians is a technician trainee enrolled in an approved academic training program, engaged in on-the-job training for a specific period of time.~~

~~(4)~~ (2) ~~All registered~~ Registered pharmacists in good standing in the state of Montana may supervise ~~more than one~~ a maximum of four registered pharmacy ~~technician~~ technicians, provided~~, in their professional judgment~~:

~~(a) a request for a ratio other than those previously defined must first be approved by the board;~~

~~(b)~~ (a) in the professional judgment of the pharmacist on duty, the policy and procedures of the ~~certified~~ pharmacy must allow for safe and accurate filling and labeling of prescriptions;

~~(c)~~ (b) the policy and procedures shall be reviewed annually. All affected supervising pharmacists and pharmacy technicians must be familiar with the contents and any changes made must be reported to the board; and

(d) remains the same but is renumbered (c).

~~(5)~~ (3) If a pharmacy desires more than ~~one~~ four ~~technician~~ technicians to work under the supervision, direction, and control of one pharmacist, the pharmacy shall obtain the prior written approval of the board. To apply for approval, the pharmacist-in-charge shall submit a pharmacy services plan to the board. The pharmacy services plan submitted shall demonstrate how the plan facilitates the provision of pharmaceutical care and shall include, but shall not be limited to the

following:

(a) through (d) remain the same.

~~(6)~~ (4) The board shall grant approval of a pharmacy service plan only when the board is satisfied that the provision of pharmaceutical care by the pharmacy will be enhanced by the increased use of technicians. An exception may be revoked by the board at any time for good cause.

(7) and (8) remain the same but are renumbered (5) and (6).

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-201, 37-7-307, 37-7-308, 37-7-309, MCA

REASON: The Survey of Pharmacy Law, conducted by the National Association of Boards of Pharmacy, lists Montana as the only state requiring a 1:1 pharmacist to pharmacy technician ratio and allowing limited exceptions. All other U.S. states now require ratios no greater than 1:2, 1:3 or 1:4, while some states have eliminated a recommended ratio entirely. No studies have linked the incidence of medication errors to the pharmacist to technician ratio, but many studies have implicated increasing pharmacist workloads directly to increased rates of medication errors. The Board determined it is therefore reasonable to amend this rule to allow for a maximum pharmacist to pharmacy technician ratio of 1:4. Increased utilization of pharmacy technicians and a corresponding decrease in the pharmacists' workload should reduce medication errors while enabling pharmacists to spend more time counseling patients and reviewing their medications. The Board notes that if for any reason the supervising pharmacist determines that patient safety is not enhanced but potentially harmed by an increased ratio, the pharmacist has the ability and the obligation to require a lesser ratio. As well, the Board reserves the right to revise the 1:4 ratio at any time for good cause to further the protection of the public.

The Board determined it is reasonably necessary to no longer restrict technicians to performing only a specific few tasks when working under an increased ratio. Supervising pharmacists may delegate to technicians only those tasks verified by the pharmacist and not requiring the pharmacist to exercise independent professional judgment. The Board decided to leave the choice of tasks to the supervising pharmacist and has amended the rule accordingly. Further, the Board is amending the rule to no longer require one technician to be a trainee while functioning under an increased ratio. The Board decided to leave the question of technician trainee use up to the discretion of the supervising pharmacist.

To provide greater clarity and further protect patient safety, the Board is amending the rule to allow Board revocation of ratio exceptions for good cause. The Board concluded that it is reasonable and necessary to specify in rule that the Board will revoke an exception allowing a greater than 1:4 ratio upon a good cause determination that public safety is at risk. Implementation cites are being amended to accurately reflect all statutes implemented through the rule.

24.174.801 GENERAL LICENSE REQUIREMENTS (1) through (3) remain the same.

(4) Upon permanent closure of a ~~certified~~ pharmacy, the original license becomes void and must be surrendered to the board within 10 days.

(5) Whenever a pharmacy permanently closes, the owner shall notify the board of the closing no later than 15 days prior to the anticipated date of closing. The notice shall be submitted in writing and shall include the following information:

(a) the date the pharmacy will close;

(b) the names and addresses of the persons who will have custody of the closing pharmacy's:

(i) prescription files;

(ii) bulk compounding records;

(iii) repackaging records; and

(iv) controlled substances inventory records; and

(c) the names and addresses of any persons who will acquire any legend drugs from the closing pharmacy, if known at the time the notice is filed.

(6) No later than 15 days after the pharmacy has closed, the owner shall submit to the board written confirmation that:

(a) all legend drugs have been either:

(i) destroyed; or

(ii) transferred to an authorized person(s), including the names and addresses of the person(s) to whom the legend drugs were transferred;

(b) controlled substances were transferred, including:

(i) names and addresses of the person(s) to whom the substances were transferred;

(ii) the substances transferred;

(iii) the amount of each substance transferred; and

(iv) the date on which the transfer took place;

(c) the DEA registration and all unused DEA 222 forms (order forms) were returned to the DEA;

(d) all pharmacy labels and blank prescriptions which were in the possession of the pharmacy were destroyed; and

(e) all signs and symbols indicating the presence of the pharmacy have been removed.

(7) Every pharmacy benefit manager (PBM) providing services or benefits in this state, which constitutes the practice of pharmacy as defined in 37-7-101(26), MCA, shall be licensed as a pharmacy with PBM endorsement in this state and shall comply with all provisions of ARM 24.174.801.

AUTH: 37-7-201, 37-7-503, MCA
IMP: 37-7-301, 37-7-321, MCA

REASON: It is reasonable and necessary to amend this rule to expand upon and clarify procedures for pharmacy closure. The Board notes that pharmacies have closed with no advance notice to the general public, creating patient safety issues when prescription refills cannot be obtained and the timing of previous refills is not readily available to the patient's physician or other provider. Under law, pharmacies are required to maintain prescription and patient refill history for a minimum amount of time, and prescription information must be available to authorized Board inspectors even though a pharmacy may have recently closed. The Board notes that a closed pharmacy's stock of prescription medications, including controlled

substances and the related order forms, could pose a significant risk of public harm if diverted. The Board determined that amending the rule to clearly delineate pharmacy closure procedures would further the goal of ensuring patient health and safety.

It is reasonable and necessary to amend this rule to clarify licensure and Board regulation of pharmacy benefit managers providing services or benefits within this state. It is unlawful to engage in the practice of pharmacy unless licensed by the Board pursuant to 37-7-301, MCA. The practice of pharmacy is defined at 37-7-101(26), MCA, and includes the modification of drug therapy. Drug product selection is regulated pursuant to title 37, chapter 7, part 5, MCA, which provides the Board's authority to adopt, amend or repeal rules to implement and enforce the section. Pharmacy benefit managers engaging in drug product selection that results in modification of drug therapy fall under the jurisdiction of the Board for regulatory purposes, as engaging in the practice of pharmacy. The addition of this section was made at the request of several citizens throughout Montana, and is being proposed by the Board in an effort to further protect public health and safety.

Authority and implementation cites are being amended to accurately reflect all statutes implemented through the rule and provide the complete sources of the Board's rulemaking authority.

24.174.806 LICENSES TO BE POSTED (1) The ~~certified~~ pharmacy license must be posted in a conspicuous place in the pharmacy.

AUTH: 37-7-201, MCA
IMP: ~~37-7-302,~~ 37-7-321, MCA

REASON: It is reasonable and necessary to amend this rule by deleting "certified" from "certified pharmacy" to clarify a potentially confusing point and add consistency in the rules. Both "pharmacy" and "certified pharmacy" are used interchangeably in 37-7-321, MCA, but "certified pharmacy" is not defined in either rule or statute. "Pharmacy" is defined in 37-7-101(23), MCA, without differentiating the term from, or further defining, "certified pharmacy". All pharmacies, regardless of the terminology used to describe them, must post their licenses in a conspicuous place. Implementation cites are being amended to accurately reflect all statutes implemented through the rule and to delete reference to an erroneous cite.

24.174.814 SECURITY OF A ~~CERTIFIED~~ PHARMACY (1) remains the same.

(a) A Schedule II controlled substance perpetual inventory shall be maintained and routinely reconciled in all pharmacies.

(2) through (4) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: It is reasonable and necessary to amend this rule by deleting "certified" from the catchphrase to clarify a potentially confusing point and add consistency in

the rules. Both "pharmacy" and "certified pharmacy" are used interchangeably in 37-7-321, MCA, but "certified pharmacy" is not defined in either rule or statute. "Pharmacy" is defined in 37-7-101(23), MCA, without differentiating the term from, or further defining, "certified pharmacy". All pharmacies, regardless of the terminology used to describe them, must maintain security against theft or diversion of drugs.

The Board determined it is reasonably necessary to amend this rule to require all pharmacies to maintain and routinely reconcile a perpetual, ongoing written or electronic inventory of its Schedule II controlled substances. Many pharmacies already engage in this safety practice, which allows the earliest possible detection of errors, miscounts or possible diversion of many of the most easily divertible and addictive medications. As a matter of public health and safety, and as perpetual inventories are rapidly becoming a recognized standard of care, the Board is amending the rule to require all pharmacies to maintain perpetual inventory records of Schedule II controlled substances purchased, stored and dispensed.

24.174.1002 CONDITIONS OF REGISTRATION (1) remains the same.

(a) be a legal entity registered and in good standing ~~in this~~ with the Montana Secretary of S~~s~~tate; ~~as a foreign corporation;~~

(b) through (f) remain the same.

AUTH: 37-7-712, MCA
IMP: 2-18-704, 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

REASON: It is reasonable and necessary to amend this rule to clarify with whom out-of-state mail service pharmacies must register and to change the term "foreign corporation" to "legal entity". In a time of ever-increasing international business ventures, the term "foreign corporation" has unnecessarily confused applicants, in some cases delaying completion of their licensure.

24.174.1107 ABSENCE OF PHARMACIST IN INSTITUTIONAL SETTINGS

(1) remains the same.

(2) If night cabinets are used to store drugs in the absence of a pharmacist, they must be locked and sufficiently secure to deny access to unauthorized persons, and must be located outside of the pharmacy area. Contents of night cabinets must be prepackaged. Only specifically authorized personnel may obtain access by key or combination, pursuant to a valid prescription order. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the facility, develop inventory listings of drugs included in these cabinet~~(s),~~ and determine who may have access~~,~~ . ~~and shall ensure that:~~

~~(a) written policies and procedures are established to implement the requirements of this rule;~~

~~(b) all drugs are properly labeled; and~~

~~(c) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements.~~

~~(3) Whenever access to the cabinet occurs, all of the following information must be recorded on or attached to a suitable form:~~

~~(a) a copy of the written practitioner's orders, showing the date and time the order was issued;~~

~~(b) identification of patient;~~

~~(c) identification of the patient's room number, if applicable;~~

~~(d) the name, strength and quantity of drug removed; and~~

~~(e) the signature of the person removing the drug(s).~~

~~(4)~~ (3) A complete verification audit of all inpatient orders and activity concerning the night cabinet or after-hours pharmacy entry must be conducted by ~~the pharmacist-in-charge or the~~ a pharmacist, pharmacy technician, or other licensed designee of that pharmacist within 48 hours of the drugs having been removed from the night cabinet or pharmacy.

(5) remains the same but is renumbered (4).

(a) Removal of any drug from the pharmacy, floor stock, or night cabinet by an authorized nurse must be recorded on a suitable form ~~left in the pharmacy~~ showing the following information:

(i) and (ii) remain the same.

(iii) the name, strength, and quantity ~~and NDC number~~ of drug removed;

(iv) through (vi) remain the same.

(b) in cases of medication not unit-dosed, the NDC number of the drug removed must also be recorded.

(5) The pharmacist-in-charge shall ensure that:

(a) written policies and procedures are established to implement the requirements of this rule;

(b) all drugs are properly labeled; and

(c) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements.

(6) A copy of the original drug order with the NDC number or other identifying code of the drug(s) provided may be faxed to the pharmacist. If the patient is an inpatient, ~~A~~ a patient profile containing the patient's name, location, allergies, current medication regimen, and relevant laboratory values must be reviewed by a pharmacist within 48 hours.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The Board determined it is reasonably necessary to amend this rule to clarify and facilitate good institutional pharmacy practice while maintaining patient safety. The Board is proposing the changes following careful consideration of comments from practitioners. Adding a requirement that contents of night cabinets be prepackaged adds an extra element of patient safety, as drug identification and expiration date follow each tablet or capsule. For medication that is not prepackaged, the National Drug Code (NDC), a unique identifying number, must be recorded by the nurse removing medication to verify that the correct drug and dose was removed. The rule is being amended accordingly.

The Board acknowledges that the pharmacist-in-charge is not always able to perform a timely verification audit of drugs removed from the night cabinet or pharmacy after hours. The Board determined that it is not necessary that the

pharmacist-in-charge be the only person able to perform a verification audit. The rule is being amended to allow another pharmacist, a pharmacy technician, or that pharmacist's licensed designee, to perform verification audits, as well. Further, the Board intended the requirement of verification audits to address the provision of inpatient medications, and the word "inpatient" has been added in (3) to clarify that.

New orders for inpatients are often ongoing, as opposed to emergent orders for outpatients that are of limited duration. It is important, therefore, that a pharmacist review pertinent aspects of the inpatient's chart including allergies, current medications and relevant laboratory values in a timely manner to verify that the new medication(s) added are appropriately dosed and do not pose dangers to the patient regarding drug-drug or drug-disease interactions or contraindications. The Board is amending the rule accordingly, to require such review to occur within 48 hours of the addition of new medication(s). The requirements of pharmacists-in-charge are not new, but were moved within the rule to new (5) for added clarity.

24.174.1111 DRUG DISTRIBUTION AND CONTROL IN AN INSTITUTIONAL FACILITY (1) through (5) remain the same.

(6) The safe handling, storage, and administration of medications within jails, correctional facilities, and detention facilities without onsite pharmacies shall be regulated as follows:

(a) Jails, correctional facilities, and detention facilities must have written policies and procedures in place, written by the responsible practitioner or authority, for the safe handling, storage, and administration of medications. Such policies shall address security of medications, procurement, proper storage and disposal of medications, training for those administering medication, methods for documenting that medications were given or refused, procedures for confirming that the inmate has ingested each medication, and the disposition of medications at discharge. Medications brought by or with an inmate upon admission to the jail, correctional facility, or detention facility must not be used unless specifically authorized by a physician at the jail, correctional facility, or detention facility or that physician's designee, and medication identity has been confirmed by a licensed health care professional. Prescription medications brought by an inmate from outside must be recorded on the inmate property record. If they are not used while the patient is incarcerated, they must be stored in a secure area until the inmate's release.

(b) Patient medications may be transferred from one jail, correctional facility, or detention facility to another if there is a secure method for ensuring that individual inmate prescriptions are not tampered with between locations and that containers are properly labeled. During transfer, medications requiring storage at room temperature should be subjected to external temperatures no greater than 86 degrees Fahrenheit. A method of transferring refrigerated medications from one jail, correctional facility, or detention facility to another must be addressed in policy and procedure. Medications transferred pursuant to the above regulations, in control of the transferring official at all time, may continue to be used for that patient.

(c) Emergency kits supplied and maintained by a registered pharmacist may be utilized if policies and procedures regulating their use are in place. Such emergency kits will comply with the requirements of ARM 24.174.1114.

(d) Jails, correctional facilities, and detention facilities without an onsite

pharmacy that procures, stores, and administers prescription medications may request technical assistance from the board.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, 37-7-406, MCA

REASON: Although the Board does not license or inspect jail facilities without in-house pharmacies, the Board is statutorily mandated to regulate the practice of pharmacy, including establishing specifications for facilities, environment, supplies, technical equipment, personnel and procedures for the storage, compounding, or dispensing of drugs and devices. If no in-house pharmacy exists, a consulting pharmacist and supplying pharmacy are involved. It is in the best interest of inmates and society as a whole that policies and procedures be written and followed that describe the safe handling, storage, administration and transfer of those medications within and between jail facilities, as well as use of medications in emergency kits supplied by registered pharmacists. The Board finds it reasonably necessary to amend this rule in an effort to assure medication safety for all Montana residents, including those incarcerated. Implementation cites are being amended to accurately reflect all statutes implemented through the rule.

24.174.1201 WHOLESALE DRUG DISTRIBUTOR LICENSING

(1) through (3) remain the same.

(4) A separate license is required for each separate location where drugs are stored. ~~within the state of Montana.~~ If a wholesaler distributes prescription drugs from more than one facility, the wholesaler must obtain a license for each facility.

~~(a) Out-of-state wholesale drug distributors who do not maintain or operate a physical facility within the state of Montana are not required to license separate locations from which drugs are shipped to Montana, but may instead obtain licensure for the primary location of the parent entity and any divisions, subsidiaries, or affiliated companies.~~

(5) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations. Wholesale drug distributors who deal in controlled substances shall register with the board ~~of pharmacy~~ and with the ~~drug enforcement administration~~ DEA, and shall comply with all applicable state, local, and ~~drug enforcement administration~~ DEA regulations.

AUTH: 37-7-201, 37-7-610, MCA
IMP: 37-7-603, 37-7-604, 37-7-605, 37-7-606, MCA

REASON: The Board determined it is reasonably necessary to amend this rule to update its regulation of the channels through which medications pass on their way to Montana patients. Counterfeit prescription medications are a significant threat to the health and safety of the patients of this state. To protect the safety of Montana's medication supply, the Board concluded that it is necessary to add language specifying the Board's licensure, regulation and inspection of all branches of a wholesaler's operation that ship medications into Montana rather than just the sole parent entity. The definition of wholesale drug distributor at 37-7-302(7), MCA,

includes all levels of an entity engaged in wholesale distribution of prescription drugs.

The definition of "DEA" has been added to ARM 24.174.301, the Board's definitions rule for simplicity and to maintain all definitions in a single rule. The Board is amending this rule accordingly.

24.174.1202 MINIMUM INFORMATION REQUIRED FOR LICENSURE

(1) through (1)(d) remain the same.

(e) the name, address, and telephone number of the owner and operator of the licensee, including:

(i) if an individual, the name, address, and telephone number of the individual;

(ii) if a partnership, the name, address, telephone number, and ownership percentage of each partner, and the name of the partnership;

(iii) if a corporation, the name, address, telephone number, and ownership percentage and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(iv) if a sole proprietorship, the full name, address, and telephone number of the sole proprietor, and the name of the business entity;

(f) the name and address of the five highest-ranking employees responsible for daily operations;

(g) the name and address of the five largest shareholders owning at least 5% of the total shares;

(h) if out-of-state, proof of corresponding licensure in good standing in the state in which the applicant resides;

(i) the federal tax identification number of the company; and

(f) remains the same but is renumbered (j).

(2) remains the same.

AUTH: 37-7-201, 37-7-610, MCA
IMP: 37-7-604, 37-7-605, MCA

REASON: It is reasonable and necessary to amend this rule to update the required information for licensure of wholesale drug distributors. It is becoming a regulatory standard to request more detailed information from wholesalers to safeguard the integrity of the state's drug supply. To further protect the health and safety of Montana's citizens, the Board is amending this rule to more strictly regulate the channels through which prescription medications pass.

24.174.1211 MINIMUM REQUIREMENTS FOR STORAGE AND HANDLING OF DRUGS (1) through (5) remain the same.

(6) A stock of prescription drugs, adequate to service the ordinary needs of practitioners and pharmacies with which the wholesaler transacts business, must be maintained.

(7) A wholesaler may not maintain a stock of controlled substances unless the wholesaler ordinarily sells controlled substances to practitioners and pharmacies with which the wholesaler transacts business.

(8) Within any calendar month, a wholesaler may not sell, distribute, transfer, or otherwise provide more than 10% of the total amount distributed of each prescription drug or drug product to another wholesaler, distributor, or manufacturer.

(9) A wholesaler may not purchase or receive back from a pharmacy a greater quantity of any prescription drug than was originally sold by the wholesaler.

AUTH: 37-7-201, 37-7-610, MCA
IMP: 37-7-604, MCA

REASON: The Board determined it is reasonably necessary to amend the rule to more strictly regulate the channels through which medications pass into this state. Counterfeit prescription drugs have penetrated the security of legitimate channels of distribution in the U.S., posing a growing risk to the health and safety of Montana's citizens. The Board is statutorily mandated with licensing and regulating lawful wholesale operations which consequently aids in the reduction of criminal establishment of phony wholesale operations. The additional requirements, all elements of legitimate wholesale operations, will help to differentiate the two.

24.174.1212 MINIMUM REQUIREMENTS FOR ESTABLISHMENT AND MAINTENANCE OF DRUG DISTRIBUTION RECORDS (1) and (1)(a) remain the same.

(b) the identity and quantity of the drugs received and distributed or disposed of; ~~and~~

(c) the dates of receipt and distribution or other disposition of the drugs~~.~~ ;

(d) evidence of the existence of a written franchise, license, or other agreement between a manufacturer and wholesaler to distribute prescription drugs;

(e) evidence of completion of two or more purchases of prescription drugs in any six month period; and

(f) a complete list of all wholesale distributors and manufacturers from whom the wholesaler purchased prescription drugs within the last year.

(2) through (5) remain the same.

AUTH: 37-7-201, 37-7-610, MCA
IMP: 37-7-604, 37-7-609, MCA

REASON: The Board determined it is reasonably necessary to amend the rule to more strictly regulate the channels through which medications pass into this state. Counterfeit prescription drugs have penetrated the security of legitimate channels of distribution in the U.S., posing a growing risk to the health and safety of Montana's citizens. The Board is statutorily mandated with licensing and regulating lawful wholesale operations which consequently aids in the reduction of criminal establishment of phony wholesale operations. The additional requirements, all elements of legitimate wholesale operations, will help to differentiate the two.

24.174.1401 REQUIREMENTS FOR REGISTRATION (1) through (4)(b) remain the same.

(c) the applicant has furnished the board a complete resume of all research proposed relative to any dangerous drugs. Such resume must be a duplicate of an application submitted to the ~~drug enforcement administration of the United States department of justice~~ DEA; and

(d) remains the same.

AUTH: 50-32-103, MCA
IMP: 50-32-306, 50-32-308, MCA

REASON: It is reasonable and necessary to define "DEA" in one centralized location within the rules. The Board is adding the definition of "DEA" to ARM 24.174.301 to provide simplicity in the rules and maintain all definitions in a single rule, and is amending this rule accordingly.

24.174.2101 ~~CERTIFIED~~ PHARMACIES - ANNUAL RENEWAL

(1) remains the same.

AUTH: 37-7-201, MCA
IMP: 37-7-321, MCA

REASON: It is reasonable and necessary to amend this rule catchphrase by deleting "certified" to clarify a potentially confusing point and add consistency within the rules. Both "pharmacy" and "certified pharmacy" are used interchangeably in 37-7-321, MCA, but "certified pharmacy" is not defined in either rule or statute. "Pharmacy" is defined in 37-7-101(23), MCA, without differentiating the term from, or further defining, "certified pharmacy". The term is being amended for consistency throughout the rules and this rule is being amended accordingly.

24.174.2401 SCREENING PANEL (1) The board screening panel shall consist of three board members, including the two pharmacist members who have served longest on the board, and one ~~public~~ other member as appointed by the board president ~~who has served longest on the board~~. The board president may reappoint screening panel members as necessary at the president's discretion.

AUTH: 37-7-201, MCA
IMP: 37-1-307, MCA

REASON: The 2003 Montana Legislature enacted Chapter 224, Laws of 2003 (Senate Bill 109), an act generally revising professional and occupational licensing laws and adding a pharmacy technician to the Board. The bill was signed by the Governor on April 3, 2003 and became effective on July 1, 2003. It is reasonable and necessary to amend this rule to reflect the change in Board composition.

4. The proposed new rules provide as follows:

NEW RULE I INACTIVE LICENSE (1) A pharmacist may obtain an inactive license through a written request to the board, if the pharmacist holds an active

Montana pharmacist license in good standing, and will not practice in Montana for the period of inactive licensure.

(2) A pharmacist with an inactive status of three years or less, whether or not the pharmacist has been in practice in another state, wishing to return to active status in Montana shall:

(a) submit a written request for status change to the board;

(b) pay either:

(i) the difference between the current inactive and active license renewal fees if the change occurs between renewal periods; or

(ii) the full active license renewal fee if the change occurs during the regular renewal period;

(c) certify that:

(i) no disciplinary action has been taken by any state or federal jurisdiction which would prevent or restrict the pharmacist's practice of the profession; and

(ii) the pharmacist has not surrendered any credential or privilege in the practice of the profession in lieu of or to avoid formal action;

(d) submit verification of active practice from the state(s) in which practice occurred; and

(e) provide proof that continuing education requirements for the period of inactive licensure have been satisfied.

(3) A pharmacist with an inactive status of three to five years, who has not been in active practice in another U.S. state, wishing to return to active status in Montana shall:

(a) comply with the requirements of (2);

(b) complete an appropriate internship of 300 hours or take and pass the North American Pharmacist Licensure Examination (NAPLEX); and

(c) take and pass the Multistate Pharmacy Jurisprudence Examination (MPJE) for the state of Montana.

(4) A pharmacist with an inactive status of five years or more, who has not been in active practice in another U.S. state, wishing to return to active status in Montana shall:

(a) comply with the requirements of (2);

(b) complete an appropriate internship of 300 hours;

(c) take and pass the NAPLEX; and

(d) take and pass the MPJE for the state of Montana.

(5) A pharmacist with an inactive status for more than three years, who has been in active practice in another U.S. state, wishing to return to active status in Montana shall:

(a) comply with the requirements of (2); and

(b) take and pass the MPJE for the state of Montana.

AUTH: 37-1-319, 37-7-201, MCA
IMP: 37-1-319, 37-7-201, MCA

REASON: It is reasonably necessary to adopt New Rule I to address inquiries and requests from practitioners both nearing retirement and working out of state regarding an inactive licensure status capable of conversion to active status upon

request and fulfillment of qualifications. Such a mechanism has proven to be a cost savings to inactive status pharmacists in other states and still permits the Board to set requirements for reentry into the profession on an active basis if the pharmacist has not practiced for years. The proposed requirements for reentry into active practice are set at several levels based upon length of inactive status and whether or not the applicant has been in active practice in another state. It is reasonable and necessary to create New Rule I to fairly license pharmacists wishing to retain their licensure while not practicing in this state and still ensure that those wishing to reenter the active practice of pharmacy are competent to do so.

NEW RULE II TELEPHARMACY OPERATIONS (1) A remote telepharmacy site shall be connected to its parent pharmacy via computer, video, and audio link.

(2) A site cannot be licensed as a remote telepharmacy site if it is located within a 10 mile radius of an existing pharmacy.

(3) A remote telepharmacy site manned by a registered pharmacy technician shall access and use the parent pharmacy's central processing unit.

(4) A remote telepharmacy site shall comply will all the requirements of pharmacy rules and statutes of Montana. The remote telepharmacy site is considered to be under the personal charge of the pharmacist at the parent pharmacy.

(a) The remote telepharmacy site must have a registered pharmacy technician present and a working computer, video, and audio link to a pharmacist at the parent pharmacy to have the prescription area open.

(b) The technician at the remote telepharmacy site must:

(i) be currently registered with the board;

(ii) be currently certified with the pharmacy technician certification board; and

(iii) have at least six months of active experience as a pharmacy technician.

(c) The technician may unlock the prescription and storage areas. While the technician is on duty, the prescription area may remain open. Security standards for pharmacies shall be maintained at all times pursuant to ARM 24.174.814.

(d) The technician will be subject to all rules of ARM 24.174.701 through 24.174.714.

(e) All prescription records and consecutive prescription numbers must be maintained at the parent pharmacy. The remote telepharmacy site must transmit copies of new prescriptions via secure electronic means to the parent pharmacy, keeping the original prescription blank at the remote telepharmacy site.

(f) Prescriptions filled at the remote telepharmacy site must be distinguishable in some manner from those filled at the parent pharmacy.

(g) Daily reports for both the parent pharmacy and remote telepharmacy site must be maintained at the parent pharmacy.

(h) The remote telepharmacy site may have a prescription inventory. Prescription medications including controlled substances shall be securely maintained at the remote telepharmacy site in accordance with current Montana pharmacy statutes and rules.

(i) If controlled substances are dispensed or handled, both the remote telepharmacy site and the parent pharmacy must be registered with the DEA and must obtain individual DEA numbers.

(j) All records must be stored at the parent pharmacy, except those required by DEA to be at a DEA registered site.

(k) The software system utilized must be able to generate labels from the parent pharmacy or at the remote telepharmacy site.

(l) The input of drug information may be done by a pharmacist at the parent pharmacy or a technician at either location if verified by a pharmacist.

(m) New prescriptions may be received at the parent pharmacy and entered there with a label printing at the remote telepharmacy site.

(n) New prescriptions received at the remote telepharmacy site may be entered into the computer system at the remote telepharmacy site. The pharmacist at the parent pharmacy remains responsible for all verification, interaction checking, and profile review.

(o) All filled prescriptions must have a label meeting the requirements of ARM 24.174.511 attached to the final drug container before the pharmacist verifies the dispensing process.

(p) Unless the remote telepharmacy site is a remote telepharmacy dispensing machine site, a pharmacist shall compare via video link the stock bottle, drug dispensed, and strength. The entire label must be checked for accuracy on the video link.

(q) The computer, video, and audio link must be operational and the remote telepharmacy site must be closed if the link malfunctions, unless a pharmacist is working at the remote site.

(r) A code containing both the pharmacist's and technician's initials must appear on the fill screen, patient profile, and prescription label.

(s) No prescription medication may be released to a patient until approved by a pharmacist in person or via the computer, video, and audio link.

(t) The pharmacist shall counsel the patient or the patient's agent via video and audio link on all new prescriptions and on refills only if the pharmacist deems necessary.

(u) When the technician is not present, dispensing and counseling via video and audio link may be done using a secure alternate delivery system with prior approval of the board.

(v) The license holder or the pharmacist in charge of the parent pharmacy shall apply for a license for the remote telepharmacy site.

(w) As dispensing is considered to be done by the pharmacist, the pharmacist shall be responsible for and held accountable for dispensing at the remote telepharmacy site.

(x) Policies and procedures must be in place to ensure the safe and effective distribution of pharmaceutical products and delivery of required pharmaceutical care.

(y) The pharmacist at the parent pharmacy shall perform an ongoing analysis of incident reports and outcomes, with appropriate corrective action taken when necessary to ensure patient safety.

(z) The pharmacist at the parent pharmacy or that person's designee shall conduct and complete monthly inspections of the remote telepharmacy site. Inspection criteria must be included in the policies and procedures for the site. The inspection report must be available for review at the next board inspection.

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-201, 37-7-321, MCA

REASON: As a sparsely populated rural state, Montana has great inconsistency in the provision of pharmacy services. Ten counties in Montana have no community pharmacy in operation, which can create a tremendous hardship for citizens of those counties. Many other rural states, including North Dakota, permit telepharmacy practice within their borders, with positive results regarding patient satisfaction and patient safety. Montana currently has one telepharmacy pilot project in operation, and the initial results have been positive.

It is reasonable and necessary to adopt New Rule II to address the practice of telepharmacy in Montana through the utilization of registered pharmacy technicians at remote sites and subject to rules protecting patient safety, confidentiality and pharmacy security. The Board determined that provision of best-practice pharmacy service in underserved areas, and not economic concerns, is the driving force behind proposed New Rule II.

NEW RULE III REMOTE TELEPHARMACY DISPENSING MACHINE SITES

(1) Remote telepharmacy dispensing machine sites contain prescription inventory which is secured in an automated dispensing device connected to the central processing unit at the parent pharmacy.

(2) A site cannot be licensed as a remote telepharmacy dispensing machine site if it is located within a 10 mile radius of an existing pharmacy.

(3) A pharmacist must approve all outpatient prescriptions before they are dispensed, unless the prescription is directly dispensed by a person authorized to prescribe.

(4) All filled prescriptions must have a label that meets the requirements of ARM 24.174.511 attached to the final drug container.

(5) A licensed pharmacist at the parent site shall perform counseling and professional consultation via audio and video link as required by ARM 24.174.903, unless the prescription is directly dispensed by a person authorized to prescribe.

(6) Registered technicians involved in stocking and removal of prescription medications under this rule must have at least 80 hours of pre-training in bar coding technology. All requirements of ARM 24.174.701 through 24.174.714 will apply, excluding the technician certification requirement of ARM 24.174.702.

(7) Policies and procedures of the parent pharmacy and the remote telepharmacy dispensing machine site must address all aspects of the telepharmacy operation, including stocking procedures and removal of outdated prescription medications.

(8) The pharmacist at the parent pharmacy shall perform an ongoing analysis of incident reports and outcomes, with appropriate corrective action taken when necessary to ensure patient safety.

(9) The pharmacist in charge of the parent pharmacy or that person's designee shall conduct and complete monthly inspections of the remote telepharmacy dispensing machine site. Inspection criteria must be included in the policies and procedures for the site. The inspection reports must be available for review at the next board inspection.

(10) Remote telepharmacy dispensing machine sites must be licensed with the board by November 30 of each year, and will be subject to random inspection by board inspectors.

(11) This rule does not apply to institutional satellite pharmacies as defined in ARM 24.174.301.

AUTH: 37-7-201. MCA
IMP: 37-7-101, 37-7-201, 37-7-321, MCA

REASON: New Rule III is a variant of proposed New Rule II, wherein the remote telepharmacy site utilizes both a registered pharmacy technician and a computerized dispensing machine at the remote site. The Board determined it is reasonably necessary to adopt New Rule III to protect patient safety, confidentiality and pharmacy security while further implementing the practice of telepharmacy in Montana by providing pharmacy services to our underserved populations.

NEW RULE IV CENTRAL FILLING BY HUB PHARMACIES

(1) Original written prescriptions may be brought to a remote pharmacy by the patient or patient's agent for filling or faxing, scanning, and physical delivery to a central hub pharmacy.

(2) Prescription refill requests may be communicated to the remote pharmacy by the patient or patient's agent and forwarded electronically or by phone to the central hub pharmacy.

(3) A pharmacist shall offer patient counseling at either the remote or central hub pharmacy for all new prescriptions and at the pharmacist's professional discretion for refills.

(4) The pharmacist in charge of the central hub pharmacy shall write, maintain, and enforce policies and procedures regarding the secure transfer of filled prescriptions to the remote pharmacy. The pharmacist shall review such policies at least annually, and the policies must contain a quality assurance program capable of tracking errors.

(5) The central hub pharmacy and remote pharmacy must renew their registration with the board by November 30 of each year, and are subject to random inspections by the board.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-321, MCA

REASON: It is reasonable and necessary to adopt New Rule IV to offer the flexible provision of pharmacy services between two licensed Montana pharmacies. New Rule IV will allow prescriptions to be filled at either a remote pharmacy, or at a central hub pharmacy and then transferred securely back to the remote pharmacy. Both pharmacies must be staffed by licensed pharmacists. Pharmacist counseling of patients may occur at either pharmacy site. The Board determined it is reasonably necessary to adopt New Rule IV to enable greater flexibility in pharmacy practice in Montana while maintaining required safeguards and ensuring patient safety, confidentiality and pharmacy security.

NEW RULE V AMBULATORY SURGICAL FACILITIES

(1) The board shall annually register and inspect all ambulatory surgical facilities in Montana, regardless of pharmacy status.

(2) In an ambulatory surgical facility without an onsite pharmacy, drug distribution must be directed by a physician or consulting pharmacist licensed to practice in Montana and who is responsible for the security, storage, and distribution of drugs within the facility.

(3) The physician director or consulting pharmacist shall provide for applicable policies and procedures to ensure:

(a) proper acquisition and secure, temperature-controlled storage of all pharmaceuticals;

(b) security and accountability of controlled substances;

(c) quality control of sterile and nonsterile pharmaceutical products including procedures for identifying, removing, and destroying outdated products;

(d) evaluation of reported medication errors and development of procedures to prevent those errors;

(e) maintenance of all required records; and

(f) compliance with all requirements of the board.

AUTH: 50-32-314, MCA
IMP: 50-32-314, MCA

REASON: The 1999 Montana Legislature enacted Chapter 273, Laws of 1999 (Senate Bill 478), an act requiring the Board to adopt rules providing for the registration of ambulatory surgical facilities. The bill was signed by the Governor and became effective on April 6, 1999, and was codified at 50-32-314, MCA. The Board determined that it is reasonably necessary to adopt New Rule V providing for the registration and regulation of the prescription drug stock of ambulatory surgical facilities and to further implement the 1999 legislation.

NEW RULE VI FEE ABATEMENT (1) The Board of Pharmacy adopts and incorporates by reference the fee abatement rule of the Department of Labor and Industry found at ARM 24.101.301.

AUTH: 37-1-131, MCA
IMP: 17-2-302, 17-2-303, 37-1-134, MCA

REASON: The Board has determined there is reasonable necessity to adopt and incorporate by reference ARM 24.101.301 to allow the Board to authorize the Department to perform renewal licensure fee abatements as appropriate and when needed, without further vote or action by the Board. The Department recently adopted ARM 24.101.301 to implement a means for the prompt elimination of excess cash accumulations in the licensing programs operated by the Department.

Adoption and incorporation of ARM 24.101.301 will allow the Department to promptly eliminate excess cash balances of the Board that result from unexpectedly high licensing levels or other atypical events. Abatement in such instances will allow

the licensees who have paid fees into the Board's program to receive the temporary relief provided by abatement. Adoption of this abatement rule does not relieve the Board from its duty to use proper rulemaking procedures to adjust the Board's fee structure in the event of recurrent instances of cash balances in excess of the statutorily allowed amount.

5. Concerned persons may present their data, views or arguments either orally or in writing at the hearing. Written data, views or arguments may also be submitted to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2305, or by e-mail to dlibsdpha@mt.gov, and must be received no later than 5:00 p.m., February 10, 2006.

6. An electronic copy of this Notice of Public Hearing is available through the Department's and Board's site on the World Wide Web at http://www.pharmacy.mt.gov. The Department strives to make the electronic copy of this Notice conform to the official version of the Notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the Notice and the electronic version of the Notice, only the official printed text will be considered. In addition, although the Department strives to keep its website accessible at all times, concerned persons should be aware that the website may be unavailable during some periods, due to system maintenance or technical problems, and that a person's technical difficulties in accessing or posting to the e-mail address do not excuse late submission of comments.

7. The Board maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this Board. Persons who wish to have their name added to the list shall make a written request which includes the name and mailing address of the person to receive notices and specifies that the person wishes to receive notices regarding all Board of Pharmacy administrative rulemaking proceedings or other administrative proceedings. Such written request may be mailed or delivered to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, faxed to the office at (406) 841-2305, e-mailed to dlibsdpha@mt.gov, or may be made by completing a request form at any rules hearing held by the agency.

8. The bill sponsor notice requirements of 2-4-302, MCA, apply and have been fulfilled.

9. Jack Atkins, attorney, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY
WILLIAM BURTON, RPH, CHAIRPERSON

/s/ DARCEE L. MOE
Darcee L. Moe
Alternate Rule Reviewer

/s/ KEITH KELLY
Keith Kelly, Commissioner
DEPARTMENT OF LABOR
AND INDUSTRY

Certified to the Secretary of State January 3, 2006